BEST AVAILABLE IMAGES

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images may include (but are not limited to):

- BLACK BORDERS
- TEXT CUT OFF AT TOP, BOTTOM OR SIDES
- FADED TEXT
- ILLEGIBLE TEXT
- SKEWED/SLANTED IMAGES
- COLORED PHOTOS
- BLACK OR VERY BLACK AND WHITE DARK PHOTOS
- GRAY SCALE DOCUMENTS

IMAGES ARE BEST AVAILABLE COPY.

As rescanning documents *will not* correct images, please do not report the images to the Image Problem Mailbox.

REMARKS

Reconsideration and withdrawal of the rejections of the application are respectfully requested in view of the amendments and remarks herewith, which place the application into condition for allowance.

I. STATUS OF CLAIMS AND FORMAL MATTERS

Claims 1-28, 30, 32 and 34 are pending. Claims 1, 6, 22-24, 27, 30 and 32 are amended and claims 29, 31 and 33 are cancelled without prejudice. New claim 34 is added.

It is submitted that these claims are patentably distinct from the prior art cited by the Examiner, and that these claims are in full compliance with the requirements of 35 U.S.C. §112. The amendments and remarks herein are not made for the purpose of patentability within the meaning of 35 U.S.C. §§ 101, 102, 103 or 112; but rather the amendments and remarks are made simply for clarification and to round out the scope of protection to which Applicants are entitled. Support for the amended recitations in the claims and the new claims are found throughout the specification and from the original claims, specifically, new claim 34 finds support in cancelled claim 29.

Attached is a corrected version (underlined) of original claims 30-33, as requested.

Also attached is a copy of the PTO 1449 document filed in the original application, as requested.

II. 35 U.S.C. §112, SECOND PARAGRAPH, REJECTIONS

Claims 1, 6, 22-24, 27, 29, 30, 32 and 33 were rejected under 35 U.S.C. §112, second paragraph, for allegedly being indefinite for failing to particularly point put and distinctly claim the subject matter which applicant regards as the invention. The rejections are traversed.

Although Applicant disagrees with the allegations that claims 1, 6, 22-24, 27, 29, 30, 32 and 33 are indefinite, the amendments to the claims renders the rejection moot.

Consequently, reconsideration and withdrawal of the Section 112, second paragraph, rejections are respectfully requested.

III. 35 U.S.C. §112, FIRST PARAGRAPH

Claims 30-33 were rejected under 35 U.S.C. §112, first paragraph for allegedly failing to comply with the written description requirement and 35 U.S.C. § 112 as being based on material added to the patent for which reissue is sought.

Although Applicant disagrees with the allegations that claims 30-33 fail to comply with section 112, the amendments to the claims render the rejection moot.

Consequently, reconsideration and withdrawal of the Section 112 rejections are respectfully requested.

IV. 35 U.S.C. § 251 REJECTIONS

Claims 30-33 were rejected under 35 U.S.C. § 251 as being based on material added to the patent for which reissue is sought and as being improper recapture of broadening claimed subject matter allegedly surrendered in the application. The rejections are traversed.

The Examiner alleges, "[t]he record of the application for the patent shows that the broadening aspect (in the reissue) relates to subject matter that applicant previously surrendered during the prosecution of the application." (*Office Action* at 5). In addition, the Examiner states that "[d]uring prosecution of the original application applicants added the limitation 'whereby the amount of Vitamin C is greater than 1000 mg' to claim 1 and argued that this is the reason why the rejection under 35 USC 102/103 should fail." (*Id.*). Further, the Examiner states that the "applicants argued the importance of the language, 'facilitating absorption of NAC across cell membranes,' in their response to the rejection under 35 USC 102/103." (*Id.*).

The Examiner in charge of the original application, however, did not allow the claims based on this amendment or argument. Rather, the claims were found allowable, for example, when claim 1 was amended to include "N-acetyl-d-glucosamine", which was agreed upon during an Examiner interview on February 9, 2001.

As the element, "whereby the amount of Vitamin C is greater than 1000 mg" did not make the claims allowable over the cited art, there is no surrendered subject matter.

Specifically, the Manual of Patent Examining Procedure (MPEP) states, "[a] reissue will not be granted to 'recapture' claimed subject matter which was surrendered in an application to obtain the original patent." MPEP § 1412.02. More specifically, under the heading CRITERIA FOR DETERMINING THAT SUBJECT MATTER HAS BEEN SURRENDERED, the alleged surrendered subject matter must make the claims allowable over a rejection or objection made in the original application:

> If the limitation now being omitted or broadened in the present reissue was originally presented/argued/stated in the original application to make the claims allowable over a rejection or objection made in the original application, the omitted limitation relates to subject matter precisely surrendered by applicant and impermissible recapture exits.

(*Id.*).

Applying the MPEP to the instant case, the only surrender of subject matter is a composition of matter comprising N-acetylcysteine and Vitamin C without N-acetyl-d-glucosamine, because the Applicants added the element N-acetyl-d-glucosamine pursuant to an Examiner interview to overcome the cited art to obtain a patent. There was no surrender of subject matter with respect to the amount of Vitamin C.

Specifically, the Examiner in the original application did not allow the claims after the Applicants' amended claim 1 to include "whereby the amount of Vitamin C is greater than 1000 mg." Similarly, the claims were not allowed after arguing that the composition facilitates

absorption of N-acetylcysteine across cell membranes. Accordingly, these elements did not make the claims allowable over the cited art and thus cannot be construed as surrendered subject matter.

As mentioned above, the claims were found allowable only after amending clam 1 to include "N-acetyl-d-glucosamine", which was agreed upon during an Examiner interview.

Consequently, reconsideration and withdrawal of the Section 251 rejections for improper recapture of broadening subject matter is respectfully requested.

V. OBJECTIONS

Claims 31 and 33 were objected as being of improper dependent form for failing to further limit the subject matter of a previous claim. Claims 31 and 33 are cancelled without prejudice.

Consequently, reconsideration and withdrawal of the objection to claim 31 is respectfully requested.

VI. OATH

Claims 1-33 were rejected under 35 U.S.C. § 251 as being based upon a defective reissue oath or declaration. A new oath or declaration from the inventors and assignee accompanies this amendment or will follow shortly.

Consequently, reconsideration and withdrawal of the rejections of claims 1-34 under 35 U.S.C. § 251 is respectfully requested.

Attached hereto is a marked-up version of the changes made to the claims by the current amendment. The attached page is captioned **"Version with markings to show changes made."**

CONCLUSION

By this Amendment, the instant claims should be allowed; and this application is in condition for allowance. Favorable reconsideration of the application, withdrawal of the rejections, and prompt issuance of the Notice of Allowance are, therefore, all earnestly solicited.

Respectfully submitted,
FROMMER LAWRENCE & HAUG LLP

By: _____

Ronald R. Santucci
Reg. No. 28,988
Tel: (212) 588-0800
Fax: (212) 588-0500

"Version with markings to show changes made"

1. (Amended) A composition of matter, which comprises in admixture;

N-acetylcysteine~~;~~, N-acetyl-d-glucosamine and vitamin C whereby the amount of vitamin C is in an amount of at least 1000 mg. or greater to facilitate the absorption of N-acetylcysteine across the cellular membrane; and, a pharmaceutically acceptable carrier for oral administration.

6. (Amended) The ~~systematic~~ systemic administration of a pharmaceutically effective amount of the composition according to claim 1 to a mammal suffering from low glutathione levels, to stimulate the natural production of glutathione in the biologically active cells of the mammal.

22. (Amended) The systemic administration ~~of a pharmaceutically effective amount of the composition~~ according to claim 19, wherein the disease is a member of the group consisting of pulmonary oxygen toxicity, adult respiratory distress syndrome, broncopulmonery dysplasia, sepis syndrome, Parkinson's disease, encephalitis, endotoxemia, anoxia induced neuronal damage, ischemic reperfusion injury, inflammatory diseases, systemic lupus erythematosis, myocardial infarction, stroke, traumatic hemorrhage, spinal cord trauma, Crohn's disease, rheumatoid arthritis, diabetes, cataract formation, uvetis, emphysema, gastric ulcers, oxygen toxicity, neoplasia, undesired cell apoptosis, radiation sickness.

23. (Amended) The systemic administration ~~of a pharmaceutically effective amount of the composition~~ according to claim 20, wherein the disease is a member of the group consisting of pulmonary oxygen toxicity, adult respiratory distress syndrome, broncopulmonery dysplasia, sepis syndrome, Parkinson's disease, encephalitis, endotoxemia, anoxia induced neuronal damage, ischemic reperfusion injury, inflammatory diseases, systemic lupus erythematosis, myocardial infarction, stroke, traumatic hemorrhage, spinal cord trauma, Crohn's disease,

rheumatoid arthritis, diabetes, cataract formation, uvetis, emphysema, gastric ulcers, oxygen toxicity, neoplasia, undesired cell apoptosis, radiation sickness.

24. (Amended) The systemic administration ~~of a pharmaceutically effective amount of the composition~~ according to claim 21, wherein the disease is a member of the group consisting of pulmonary oxygen toxicity, adult respiratory distress syndrome, broncopulmonery dysplasia, sepis syndrome, Parkinson's disease, encephalitis, endotoxemia, anoxia induced neuronal damage, ischemic reperfusion injury, inflammatory diseases, systemic lupus erythematosis, myocardial infarction, stroke, traumatic hemorrhage, spinal cord trauma, Crohn's disease, rheumatoid arthritis, diabetes, cataract formation, uvetis, emphysema, gastric ulcers, oxygen toxicity, neoplasia, undesired cell apoptosis, radiation sickness.

27. (Amended) The ~~probiotic~~ composition of claim ~~1~~26, wherein said probiotic is a composition of "healthy bacteria" containing one or more of said healthy bacteria selected from the group comprising bifidobacterium longum, bifidobacterium infantis, lactobacillus acidophilus, lactobacillus casei, lactobacillus rhamnosus, saccharomyces boulardi, propionibacteria and enterococci.

29. (Cancelled).

30. (Amended) A composition of matter which comprises in admixture, N-acetylcysteine~~:~~, N-acetyl-d-glucosamine and vitamin C ~~present in an amount by weight of 2 to 40 parts N-acetylcysteine, 1 to 4 parts N-acetyl-d-glucosamine and 1-4 parts vitamin C~~; and

a pharmaceutically acceptable carrier for oral administration.

31. (Cancelled).

32. (Amended) The systemic administration of a pharmaceutically effective amount of the composition of claim 30 to a mammal suffering from low glutathione levels, to stimulate the natural production of glutathione in the biologically active cells of the mammal.

33. (Cancelled).

34. (New) A method of promoting the biosynthesis of mucosal glycoproteins and/or facilitating the absorption of N-acetylcysteine into a gastrointestinal tract of a mammal, comprising the step of administering the composition of claim 1.

Corrected Version of Reissue Claims

30. (New) A composition of matter which comprises in admixture, N-acetylcysteine: N-acetyl-d-glucosamine vitamin C present in an amount by weight of 2 to 40 parts N-acetylcysteine, 1 to 4 parts N-acetyl-d-glucosamine and 1-4 parts vitamin C; and

a pharmaceutically acceptable carrier for oral administration.

31. (New) A composition of matter according to claim 30 wherein the admixture comprises 1.5 parts N-acetylcysteine, 1 part N-acetyl-d-glucosamine and 2 parts vitamin C.

32. (New) The administration of a pharmaceutically effective amount of the composition of claim 30 to a mammal.

33. (New) The administration of a pharmaceutically effective amount of the composition of claim 31 to a mammal.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s)	:	Robert H. Keller et al.
Application to Reissue Patent No.	:	6,262,019
Issued	:	July 17, 2001
For	:	METHOD OF TREATING GLUTATHIONE DEFICIENT MAMMALS

SUPPLEMENTAL DECLARATION OF ROBERT H. KELLER AND DAVID KIRCHENBAUM

As a below-named inventor, we hereby declare that:

1. Our residences, post office addresss and citizenships are as stated below next to our names.

2. We verily believe ourselves to be original, first and joint inventors of the invention described and claimed in Letters Patent No. 6,262,019 and in the specification filed for which we solicit a patent.

3. We hereby state that we have reviewed and understand the contents of the aforementioned specification, including the claims.

4. We acknowledge the duty to disclose information which is material to the examination of this application in accordance with Title 37, Code of Federal Regulations, § 1.56(a).

5. We do not know and do not believe that the invention was ever known or used in the United States of America before our invention thereof.

6. We verily believe the original Letters Patent to be wholly or partly inoperative or invalid by reason of my claiming more or less than I had a right to claim in the patent.

7. We did not discover that the claims of the original patent claimed more or less than we had a right to claim until after the original patent was issued.

8. All errors being corrected in this reissue application arose without any deceptive intention on our part.

9. New claims 30, 31, 32, and 33 submitted with this application particularly point out subject matter which we considered our invention and round out the scope of protection to which we are entitled. By the omission of such claims the original patent claims less than we had a right to claim. We did not realize at the time the application was drafted that we had the right to additionally claim compositions of matter and systems of administration thereof having an admixture including N-acetylcysteine, N-acetyl-d-glucosamine and vitamin C present in ratios set forth in new claims 30-33 submitted in the reissue application.

We hereby appoint Ronald R. Santucci, Registration No. 28,988, of Frommer Lawrence & Haug LLP or their duly appointed associate(s), our attorneys, with full power of substitution and revocation, to prosecute this application, to make alterations and amendments therein, to file continuation and divisional applications thereof, to receive the Patent, and to transact all business in the U.S. Patent and Trademark Office and in the Courts in connection therewith, and specify that all communications about the application are to be directed to the following address:

Ronald R. Santucci, Esq.
c/o Frommer Lawrence & Haug LLP
745 Fifth Avenue
New York, New York 10151

Direct all telephone calls to: (212) 588-0800 to the attention of Ronald R. Santucci, Esq.

Wherefore we pray that we may be allowed to surrender the Letters Patent No. 6,262,019 granted July 17, 2001, whereof Vit-Immune L.C., on whose behalf and with whose assent this application is made, is the sole owner, by Assignment, and that Letters Patent may be reissued to Vit-Immune L.C. for the same invention upon the attached specification.

We, the undersigned applicants, further declare that all statements made herein of our own knowledge are true and that all statements made on information and belief are believed

to be true; and further that these statements are made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

R H Keller

Robert H. Keller

6/7/04

Date

Residence: Hollywood FLA

Citizenship: USA

David Kirchenbaum

David Kirchenbaum

6/7/04

Date

Residence: Sunny Isles, Fla

Citizenship: USA

Post Office Address of Inventors:

5821 Hollywood Blvd
Hollywood FLA 33021

INFORMATION DISCLOSURE CITATION

(Use several sheets if necessary)

Docket Number (Optional)	Application Number
4250-2	09/302,217
Applicant(s)	
Keller et al.	
Filing Date	**Group Art Unit**
4/29/99	1654

U.S. PATENT DOCUMENTS

*EXAMINER INITIAL		DOCUMENT NUMBER		NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
ST		5,696,109	12/09/97	Malfroy-Camine et al.			

FOREIGN PATENT DOCUMENTS

	REF	DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	Translation YES	Translation NO

OTHER DOCUMENTS *(Including Author, Title, Date, Pertinent Pages, Etc.)*

ST		"Screening of Potential Chemopreventive Agents Using Biochemical Markets of Carcinogenesis" by Sheela Sharma, Jill D. Stutzman, Gary J. Kelloff and Vernon E. Steele, Cancer Research 54, 5848-5855, November 15, 1994.

EXAMINER	DATE CONSIDERED
Stephen Tu	08/11/2000

EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP Section 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

INFORMATION DISCLOSURE CITATION

(Use several sheets if necessary)

Docket Number (Optional)	Application Number
4250-2	09/302,217
Applicant(s)	
Robert H. Keller et al.	
Filing Date	**Group Art Unit**
4/29/99	1646

U.S. PATENT DOCUMENTS

EXAMINER INITIAL	REF	DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
ST		4,256,760	3/81	Los			
ST		4,277,496	7/81	Los			
ST		4,292,403	9/81	Duermeyer			
ST		5,290,571	3/94	Bounous et al.			
ST		5,456,924	10/95	Bounous et al.			

FOREIGN PATENT DOCUMENTS

	REF	DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	Translation YES	Translation NO

OTHER DOCUMENTS *(Including Author, Title, Date, Pertinent Pages, Etc.)*

ST		LOW BLOOD GLUTATHIONE LEVELS IN HEALTHY AGING ADULTS, pp 720-725, Calvin A. Long, et al.
ST		a-LIPOIC ACID: BIOLOGICAL EFFECTS AND CLINICAL IMPLICATIONS, pp 177-183, Trent W. Nichols, Jr. M.D.

EXAMINER	DATE CONSIDERED
[signature]	8/16/2000

EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP Section 609; Draw line through citation if not in conformance and considered. Include copy of this form with next communication to applicant.

INFORMATION DISCLOSURE CITATION

(Use several sheets if necessary)

Docket Number (Optional)	Application Number
4250-2	09/302,217
Applicant(s)	
Robert H. Keller et al.	
Filing Date	**Group Art Unit**
09/302,217	1646

EXAMINER INITIAL		OTHER DOCUMENTS *(Including Author, Title, Date, Pertinent Pages, Etc.)*
ST		GLUTATHIONE: SYSTEMIC PROTECTANT AGAINST OXIDATIVE AND FREE RADICAL DAMAGE, pp 155-171, 173-176, Parris M. Kidd, Ph.D.
ST		IMPORTANCE AND REGULATION OF HEPATIC GLUTATHIONE, pp 251-266, Laurie D. Deleve, M.D., Ph.D. et al.
ST		PROBIOTICS IN HUMAN MEDICINE, pp 439-442, R. Fuller
ST		AIDS WASTING SYNDROME AS AN ENTERO- METABOLIC DISORDER: THE GUT HYPOTHESIS, pp 40-45, 47-53, Mitchell Kaminski, Jr., M.D., et al.
ST		THE EFFECTS OF L-GLUTAMINE, N-ACETYL-D-GLUCOSAMINE, GAMMA-LINOLENIC ACID AND GAMMA-ORYZANOL ON INTESTINAL PERMEABILITY

EXAMINER	DATE CONSIDERED
Stephen Sa	8/11/2000

*EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP Section 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.